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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,739	12/11/2001	Satoshi Ono	216367USOPCT	1742

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
SMALL, ANDREA D SOUZA	
ART UNIT	**PAPER NUMBER**
1626	

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,739	ONO ET AL.	
	Examiner	Art Unit	
	Andrea D Small	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 9-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-17,19-28, 30,31* is/are allowed.

6)☒ Claim(s) *18,29 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

I. Preliminary Matters:

(a) Applicants response has been received and entered into the file.

- Claims 2-8 have been cancelled.
- Claims 9-32 have been newly added.
- Claims 1 and 9-32 are pending.

II. Remarks:

(a) Restriction/Election:

The claims 1 and newly added claims 9-32 have been amended commensurate with the scope of the elected group identified in the office action of April 1, 2003.

(b) Rejections under 35 USC 112, second paragraph:

The amendment to claim 1 and cancellation of claims 2-3 and 6-8 have overcome the rejections cited under this paragraph.

III. New Rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(a) Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The phrase "A crystal of the compound of formula I" appears nowhere in the specification or originally filed claims. In fact, the only mention of crystals is seen on page 69 of the specification , which states:

> In cases where the compounds of general formulas [2], [3], [4], [7], [8], [12], [13], [15], [15a], [15b], [16], [16b], [17], [17a], [18], [19], [20], [21], [22], [23], [24], [25], [26], [27], [28], [29], [30], [31], [32], [33], [34], [35], [36], [37], [38] and [39] have an isomer such as optical isomer, geometrical isomer, tautomer or the like, all these isomers can be used in the present invention. Further, hydrated products and solvated products and all the crystal form thereof are also usable.

This mention is insufficient to support a crystal of the compound of claim 1, which is the compound of formula I. The reference does not describe the spectral data of this crystal, the melting and boiling points, it does not describe whether this characteristic may be attributable to all the compounds within the genus or merely a few. It does not describe whether the crystals are of the compound, or in fact of the hydrated or solvated products. Thus, claim 18, drawn to a crystal of the compound of claim 1 lacks description in the specification and adds new matter into the claims.

(b) Claim 29 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating neurodegenerative diseases wherein Aβ is involved, does not reasonably provide enablement for every neurodegenerative disease which has no influence from Aβ involvement. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification does not give any guidance as to the full range of neurodegenerative disease which could be treated using the instant claimed process. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

In the instant case, Applicants are claiming a method of treating newurodegenerative disease by administering the compound of claim 1.

1. the nature of the invention:

The nature of the pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities.

2. the state of the prior art:

Currently, the state of the art in treatment of neurodegenerative diseases is such that there is no absolute knowledge as to causative mechanisms for each of the varied disease conditions that fall within the broad class of neurodegenerative diseases, let alone knowledge of the solutions to treating any one of the diseases, let alone the entire class.

3. the predictability or lack thereof in the art:

The predictability of the effectiveness of treatment from one disease to the next within the class is very low. For instance, a treatment for a prion disease resulting in Alzheimer's disease is not extendable to treatment of Huntington disease within the same class of neurodegenerative disease states. See the Hardy reference provided.

4. the amount of direction or guidance present:

Although this topic has been written on extensively, there is very little guidance present as to the mechanisms of action and the corresponding mechanisms of treating each disease, let alone the entire class of these diseases.

5. the presence or absence of working examples:

In the instant case, the only working examples are those to the effect of inhibiting the death of a cultured nerve cell induced by Aβ. The working examples are not drawn to other known mechanisms of causation of some of the neurodegenerative disease states, for example, prion diseases that result in Alzheimer's, Huntingdon disease, etc.

6. the breadth of the claims:

The breadth of the claim cover diseases states that are not a result of the nerve cell death induced by Aβ as well as those neurodegenerative disease that have not nexus with nerve cell death induced by Aβ.

7. the quantity of experimentation needed:

The quantity of experimentation needed to test each of the neurodegenerative diseases within the class to first determine if they are caused by nerve cell death induced by Aβ and then to test if the disease is then treatable by administering the compound of claim 1, would be undue.

and

8. the level of the skill in the art:

Although, the level of skill in the art is high, the unpredictability and current knowledge in the art would not lend even a highly skilled artisan with the ability to practice the invention to the extend of the scope of the claim without undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(A) Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "protecting" in claim 32 is a relative term which renders the claim indefinite. The term "protecting" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

(B) Claim 18 rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Claim 18 recites the limitation "crystal of the compound of claim 1". There is insufficient antecedent basis for this limitation in the specification.

IV. Finality:

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

V. Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrea D. Small, whose telephone number is (703) 305-0811. The examiner can normally be reached on Monday-Thursday from 8:30 AM - 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Joseph.McKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1234

Andrea D. Small, Esq.
September 17, 2003

Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626
Technology Center 1